Misbranding, Section 502 (a), the label statement "Each Capsule Contains: Vitamin A * * * 4000 U. S. P. Units * * * Vitamin C * * * 30 mg." was false and misleading as applied to the article, which contained less than 4000 U. S. P. units of vitamin A and less than 30 milligrams of vitamin C per capsule; and, Section 503 (b) (4), the article was a drug subject to Section 503 (b) (1) (B), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

Sedamar elixir. Adulteration, Section 501 (c), the strength of the article differed from that which it purported or was represented to possess, namely, 1 milligram of vitamin B_6 per teaspoonful. Misbranding, Section 502 (a), the label statement "Each Teaspoonful * * * Contains * * * Vitamin B_6 1 mg." was false and misleading as applied to the article, which contained less than 1 milligram of vitamin B_6 per teaspoonful; and, Section 503 (b) (4), the article was a drug subject to Section 503 (b) (1) (B), and its label failed to bear the statement "Caution: Federal law prohibits dispensing without prescription."

DISPOSITION: June 29, 1953. Default decree of condemnation and destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS*

4226. Misbranding of herbal preparations. U. S. v. 1 Drum, etc. (F. D. C. No. 34951. Sample Nos. 54977–L to 54985–L, incl.)

LIBEL FILED: April 21, 1953, Northern District of Illinois.

ALLEGED SHIPMENT: Between the approximate dates of October 26, 1951, and October 22, 1952, from Jersey City, N. J.

PRODUCT: 1 80-pound drum of *Formula #8*, 42 6-ounce cartons of *Nervix*, 26 6-ounce cartons of *Gastrix*, 75 6-ounce cartons of *Liverix*, 1 100-pound drum and 1 40-pound drum of *Formula #7*, 60 6-ounce cartons of *Rheumatix*, 1 90-pound drum of *Formula #10*, 10 6-ounce cartons of *Reducerix*, 3 5-ounce cartons of *Urix*, 2 6-ounce cartons of *Anti-Diabetix*, 1 25-pound drum of *Formula #6*, 48 6-ounce cartons of *Chestix*, 1 75-pound drum of *herb mixture for the bath*, and 13 6-ounce cartons of *Bathix* at Chicago, Ill., in the possession of Father Francis' Herbs, together with a number of loose labels relating to the products.

RESULTS OF INVESTIGATION: The articles contained in the cartons had been shipped in bulk, and upon their receipt by the consignee, Father Francis' Herbs, were repackaged into cartons and relabeled as described below. The articles in the drums represented portions of the bulk shipments received by the consignee which had not been at the time of seizure repackaged by the consignee.

Examination of the articles disclosed that they consisted of mixtures of ground plant material. It was assumed for purposes of the action that the articles contained the ingredients which they were represented to contain, namely, (*Formula #8* and *Nervix*) passionflower herb, white willow bark, hawthorne berries, and sweet orange peel; (*Gastrix*) "Johns-wort" herb, knotgrass, woodruff herb, T V senna leaves, juniper berries, buckthorn bark, and peppermint leaves American; (*Liverix*) St.-Johns-wort herb, boldo leaves, buckthorn bark, juniper berries, and knotgrass; (*Formula #7* and *Rheumatix*) knotgrass, horsetail rush, elder flower, ginseng root, buckthorn bark, mistletoe

*See also No. 4239 (veterinary preparation).

leaves and twigs, and coriander seed; (*Formula #10* and *Reducerix*) bladder-wrack, goldenrod herb, mistletoe leaves and twigs, sundew herb, buckthorn bark, knotgrass, and star anise seed; (*Urix*) Herniaria glabra, apium petroselinum, orthosyphon stamineus, betula alba, centaurea cyanus, and arbutus uva-ursi (knotweed, parsley, Java tea, white birch, corn flower and uva-ursi); (*Anti-Diabetix*) Hb. Equiseti Arvense, Hb. Hiperici, Fol. Myrtillorum, Fol. Vaccinii Vitis Idaea, Fol. Fragariae, Fol. Calagae Off., Fol. Urticae, Flores Tiliac, Folliculi Phaesoli, Rriz. Craminis, and Rad. Inulae Heleni (horsetail, St.-Johns-wort, myrtle leaves, mountain cranberry leaves, strawberry leaves, galangal leaves, nettle leaves, linden flowers, bean pods, triticum, and inula); (*Formula #6* and *Chestrix*) Verbascum Thapsus, Salvia Officinalis, Pimpinella Anisum, Cetraria Islandica, Symphytum Officinale, and Panax Ginseng (mullein, sage, anise, Iceland moss, comfrey, and ginseng); (*herb mixture for the bath* and *Bathix*) bladder-wrack, rosemary leaves, rosebuds, lemon verbena, orrisroot, thyme, lavender flowers, peppermint, and sage leaves.

LABEL, IN PART: (Drums) "Formula #8 [or "Formula #7" or "Formula #10"] * * * Caution—For Manufacturing Processing or Repacking," "Special Formula #6," and "Herb Mixture For the Bath"; (cartons) "Father Francis' Herbs * * * Nervix [or "Gastrix," "Liverix," "Rheumatix," "Reducerix," "Urix," "Anti-Diabetix," "Chestix," and "Bathix"] (Brand)."

NATURE OF CHARGE: *Formula #8* and *Nervix*. Misbranding, Section 502 (a), the statements on the carton label, namely, (in English and Polish) "For Nerves and Sleeplessness * * * To calm and strengthen the nervous system * * * To bring sleep" were false and misleading since the statements represented and suggested that the article was an adequate and effective treatment for nervous disorders and sleeplessness, whereas the article was not an adequate and effective treatment for nervous disorders and sleeplessness.

Gastrix. Misbranding, Section 502 (a), the label designation "Gastrix" and the statement on the carton label (in English and Polish) "For * * * Indigestion" were false and misleading since the article was not effective for gastric disorders and indigestion; Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; and, Section 502 (f) (2), its label failed to bear such adequate warnings against unsafe dosage and duration of administration, in such manner and form, as are necessary for the protection of users since its labeling failed to warn that, if used as directed in its labeling, namely, "Once or twice daily, pour a cup of boiling water over a tablespoonful of herbs, let draw about an hour, strain, and drink before bedtime, or in the morning," it may cause dependence upon laxatives to move the bowels.

Liverix. Misbranding, Section 502 (a), the label designation "Liverix" and the statement on the carton label "To promote and help regular functions of the Liver and Gall Bladder" were false and misleading since the article was not effective for disorders of the liver and was not effective to promote and help regular functions of the liver and gallbladder; and, Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient. Further misbranding, Section 502 (f) (2), the labeling failed to bear adequate warnings to the effect that, if used frequently or continuously or as directed in the labeling, namely, "2 or 3 times daily, pour a glass of boiling water over 1 tablespoonful of herbs, boil for 3 minutes, let draw about an hour, strain, add

honey if desired and drink before meals," it may cause dependence upon laxatives to move the bowels; and that it should not be used when there was nausea, vomiting, abdominal pain, or other symptom of appendicitis.

Formula #7 and *Rheumatix*. Misbranding, Section 502 (a), the label designation "Rheumatix" and the following statements on the carton label (in English and Polish) "For Rheumatism, Gout, Arthritis" and (in English) "Rheumatism is to be regarded as the name standing for similar troubles such as Neuritis, Sciatica, Lumbago, Muscular Chill, and all muscular Pain" were false and misleading since such statements represented and suggested that the article was an adequate and effective treatment for such disease conditions, when such was not the case.

Formula #10 and *Reducerix*. Misbranding, Section 502 (a), the label designation "Reducerix" and the following statement on the carton label (in English and Polish) "For Obesity and Overweight" were false and misleading since the article was not effective for reducing obesity and overweight; Section 502 (e) (2), the article was fabricated from two or more ingredients, and its label failed to bear the common or usual name of each active ingredient; and, Section 502 (f) (2), its labeling failed to bear adequate warnings to the effect that, if used frequently or continuously or as directed in the labeling, namely, "Twice daily, pour a glass of boiling water over 1 or 2 tablespoonfuls of herbs, boil for 5 minutes, allow to cool, strain, and drink before breakfast and bedtime," it may cause dependence upon laxatives to move the bowels.

Urix. Misbranding, Section 502 (a), the label designation "Urix" and the statement on the carton label "For Kidneys and Bladder" were false and misleading since the article was not effective for diseases of the kidneys, bladder, and other organs of the urinary tract.

Anti-Diabetix. Misbranding, Section 502 (a), the label designation "Anti-Diabetix" and the statement on the carton label "To promote and help regular functions of the Pancreas (Sugar Diabetes)" were false and misleading since the article was not effective to promote and help regular functions of the pancreas or for diabetes.

Chestix. Misbranding, Section 502 (a), the label designation "Chestix" and the statement on the carton label "For Coughs, Colds, Bronchitis and Lung Troubles" were false and misleading since the article was not effective for diseases of the chest, coughs, colds, bronchitis, and lung troubles.

Herb mixture for the bath and *Bathix*. Misbranding, Section 502 (a), the statement on the carton label "For * * * Strengthening Bath and Douche" was false and misleading since the article was not effective as a strengthening bath and douche; and, Section 502 (f) (2), the labeling of the article failed to bear such adequate warnings against unsafe duration of administration, in such manner and form, as are necessary for the protection of users since its labeling failed to warn that frequent use as a douche may be harmful.

The articles were misbranded in the above respects while held for sale after shipment in interstate commerce.

DISPOSITION: June 9, 1953. Default decree of condemnation and destruction.

4227. Misbranding of Niagara device. U. S. v. 66 Kits, etc. (F. D. C. No. 35344. Sample Nos. 6708–L, 45200–L.)

LIBEL FILED: June 29, 1953, District of Massachusetts.

ALLEGED SHIPMENT: The devices and certain printed matter were shipped by the Niagara Mfg. & Distributing Corp. of Adamsville, Pa., from Lansdowne,